

PATENT APPLICATION

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Title: ~~Composite Ventilation Tube~~

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BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to medical ventilation tubes and, more particularly, to myringotomy ventilation tubes that can be placed in the tympanic membrane of the ear to drain fluid and alleviate a buildup or reduction of pressure in the middle ear.

DESCRIPTION OF THE PRIOR ART

The installation of tubes in the tympanic membrane, which separates the middle ear from the outer ear, is a well-known remedy for treating inflammation of the middle ear or otitis media. Typically, a myringotomy is performed to create an opening in the tympanic membrane and a vent or drain in the form of a tube is inserted into the opening to permit drainage of fluid from the middle ear to alleviate a buildup or reduction of pressure in the middle ear cavity. The tube functions to maintain the opening in the tympanic membrane for a sufficient period of time following the surgery to allow pressure to equalize between the middle and outer ears. Frequently, the condition of buildup or reduction of pressure in the middle ear cavity which the tube is intended to alleviate requires that the tube remain in place for a significant period of time ranging in duration from about six to about twenty four months.

A variety of ventilation tubes for insertion into an opening in the tympanic membrane have been introduced over the years.

1 Prior art ventilation tubes without flanges at either end are easy
2 to insert into the myringotomy opening but are disadvantageous in
3 that they can be accidentally extracted from the tympanic membrane.
4 On the other hand, ventilation tubes having flanges at one or both
5 ends are less likely to be accidentally extracted from the tympanic
6 membrane but are difficult to insert into and extract from the
7 myringotomy openings, tending to enlarge the myringotomy openings
8 such that the tendency of the tubes to fall out of the membrane
9 increases. Attempts to fabricate prior art ventilation tubes of
10 softer materials help alleviate problems associated with insertion
11 and removal of the tubes through openings in the tympanic membrane
12 but contribute to problems related to bending or buckling of the
13 tubes during insertion while detracting from the ability of the
14 tube to maintain an opening in the tympanic membrane.

15 SUMMARY OF THE INVENTION

16 Accordingly, it is a primary object of the present invention
17 to overcome the disadvantages of the prior art and to improve
18 ventilation tubes of the type used in maintaining an opening in
19 anatomical structures such as the tympanic membrane.

20 It is another, more specific, object of the present invention
21 to ease insertion of a ventilation tube into an opening in an
22 anatomical structure while preventing inadvertent extrusion and
23 facilitating removal.

24 Yet another object of the present invention is to prevent
25 enlargement of an opening in an anatomical structure, such as the

1 tympanic membrane, in response to insertion or removal of a medical
2 ventilation tube through the opening.

3 Still another object of the present invention is to form a
4 ventilation tube as a composite structure made of two or more
5 materials of different durometer.

6 It is a further object of the present invention to maintain an
7 opening in an anatomical structure by use of a ventilation tube
8 having a hollow shaft made of a rigid or hard material and a flange
9 formed at a distal end of the shaft made of a softer, more flexible
10 material.

11 The present invention is generally characterized in a medical
12 ventilation tube for placement in an anatomical structure including
13 a hollow tubular shaft having a passage formed therethrough, the
14 hollow tubular shaft being made of a first material having a
15 rigidity to resist bending and maintain the passage in an open
16 condition when the ventilation tube is placed in the anatomical
17 structure, and a flange extending outwardly from the hollow tubular
18 shaft, the flange being made of a second material having a rigidity
19 less than that of the first material to permit the flange to deform
20 in response to contact with the anatomical structure. The first
21 material is preferably a polymer having a durometer no greater than
22 about 100 on the Shore A hardness scale, and the second material is
23 also preferably a polymer having a durometer less than that of the
24 first material but greater than about 20 on the Shore A hardness
25 scale. In a most preferred embodiment, the first material is a
26 polymer having a durometer of about 90 to about 95 on the Shore A

1 hardness scale and a second material is a polymer having a
2 durometer of about 50 on the Shore A hardness scale.

3 Another aspect of the present invention is generally
4 characterized in a method of making a medical ventilation tube
5 including the steps of forming a hollow tubular shaft from a first
6 material having a rigidity to resist bending and to maintain a
7 passage through the shaft when the ventilation tube is placed in an
8 anatomical structure, and molding a flange onto the hollow tubular
9 shaft using a second material having a rigidity less than that of
10 the first material to permit the flange to be deformed in response
11 to contact with the anatomical structure.

12 Some of the advantages of the present invention are that the
13 ventilation tube can be inserted into an opening in an anatomical
14 structure, such as the tympanic membrane, without buckling or
15 bending of the hollow shaft, that extrusion of the ventilation tube
16 is prevented while maintaining a passage of substantially constant
17 diameter through the opening, and that the ventilation tube can be
18 formed using a wide range of materials having a variety of
19 properties suitable for improving ease of insertion and removal,
20 preventing extrusion and maintaining structural rigidity of the
21 ventilation tube.

22 Other objects and advantages of the present invention will
23 become apparent from the following description of the preferred
24 embodiments taken in conjunction with the accompanying drawings,
25 wherein like parts in each of the several figures are identified by
26 the same reference characters.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top plan view, partly in section, showing a ventilation tube according to the present invention.

Fig. 2 is a fragmentary side view of the ventilation tube of Fig. 1.

Fig. 3 is a front elevational view of the ventilation tube of Fig. 1.

Fig. 4 is a fragmentary side view, in section, taken through line 4-4 in Fig. 1.

Fig. 5 is an exploded perspective view of a mold used in fabricating a ventilation tube according to the present invention.

Figs. 6 - 10 are fragmentary sectional side views illustrating a method of making a ventilation tube according to the present invention.

Fig. 11 is a perspective view, partly in section, illustrating use of a ventilation tube according to the present invention.

Fig. 12 is a fragmentary side view, partly in section, showing a modification of the ventilation tube according to the present invention.

Fig. 13 is a fragmentary side view, partly in section, showing another modification of the ventilation tube according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The medical ventilation tube of the present invention can be used to maintain an opening in any anatomical structure within the body; and, accordingly, while the ventilation tube is described herein as a myringotomy ventilation tube for placement in an opening formed in the tympanic membrane of the ear, it will be appreciated that the medical ventilation tube of the present invention can be placed in other naturally occurring and surgically created openings throughout the body.

A ventilation tube 10 according to the present invention, as shown in Figs. 1 - 4, includes a hollow tubular body or shaft 12 and a flanged end portion 14. Shaft 12 is formed of a right circular cylinder 16 with a proximal end 18, a distal end 20 and a lumen 22 extending between the proximal and distal ends to define at least part of a passage through an anatomical structure such as the tympanic membrane of the ear. Shaft 12 is preferably made of a medically acceptable plastic or metal material having a hardness or durometer suitable for withstanding axial insertion forces without buckling or bending and for maintaining the passage in a substantially unobstructed, open condition to permit drainage and ventilation of the middle ear over extended periods of time.

End portion 14 includes a cylindrical section 24 extending from the distal end of shaft 12 to a transverse cross-member or flange 26. As best seen in Fig. 2, flange 26 is generally semi-cylindrical in cross-section with a concave side 28 facing distally and a convex side 30 facing proximally to form an abutment surface

for contacting the tympanic membrane of the ear around the myringotomy opening. A pair of semi-circular cut-outs or notches 32 and 34 are formed along distal edges 36 and 38 of the flange in opposed relation near the center of the flange to permit bending of the flange from the transverse position shown in Fig. 1 to a collapsed position facilitating removal of the ventilation tube from the tympanic membrane without enlargement of the myringotomy opening. In the collapsed position, opposed ends or ears 40 and 42 of the flange are pivoted about notches 32 and 34 into mating contact along a longitudinal axis of the ventilation tube where they cooperate to form a tubular extension similar in diameter to shaft 12. Cylindrical section 24 and flange 26 are preferably formed as an integral one-piece construction using a medically acceptable metal or plastic material having a hardness or durometer less than that of the shaft to facilitate bending of the flange during insertion and removal of the ventilation tube so as to minimize trauma to the tympanic membrane.

In a preferred embodiment, shaft 12 and flanged end portion 14 are formed of a polymeric material known as C-Flex thermoplastic elastomer. The basic formula of the C-Flex material is described in U.S. Patent Nos. 4,386,179 and 4,613,640, the disclosures of which are incorporated herein by reference. Briefly, the base component of the C-Flex material is a Styrene-Ethylene/Butylene-Styrene block copolymer (SEBS). Other components, such as silicone oil, mineral oils, and polypropylene can be added in varying ratios to obtain a desired durometer. "Durometer," as used herein, refers

to the hardness of a polymer measured using the Shore A, one second scale for plastics or ASTM Method 2240. From a practical standpoint, the durometer of the shaft and flanged end portion of the ventilation tube can vary within the range of about 20 to about 100, so long as a durometer differential is maintained whereby the shaft material is of higher durometer than the flange material. Shaft 12 is preferably formed of a C-Flex polymer or similar material having a durometer of about 90 to about 95. End portion 14 is preferably formed of a C-Flex polymer or similar material having a durometer of about 45 to about 55. Examples of other polymeric materials that can be used include Teflon, Silicone and PTFE. An advantage of forming the shaft and flanged end portion of similar materials, such as the C-Flex polymers, is that they can be readily fused or bonded together to form a secure attachment that will not separate during normal implantation and removal procedures.

The ventilation tube 10 described thus far resembles in size and shape a conventional ventilation tube of the type sometimes referred to as a "Goode T-Tube." It will be appreciated, however, that the shaft and flanged end portion of the present invention can be configured in numerous other ways to resemble any type of ventilation and drain tube having a tubular shaft and a flange at one or both ends of the shaft. For example, the ventilation tube of the present invention could resemble in size and shape Touma T-Type, Donaldson, Armstrong, Pope, Collar Button, Per-Lee or Baldwin Butterfly type ventilation tubes.

1 The shaft 12 and end portion 14 of the ventilation tube 10 can
2 be fabricated using any suitable manufacturing process and can be
3 secured to one another by thermal or adhesive bonding or by
4 mechanical attachment. A preferred manner of forming the medical
5 ventilation tube 10 is by molding the flanged end portion 14 with
6 the shaft 12 positioned in the mold such that the flanged end
7 portion is formed simultaneously with attachment of the shaft. As
8 shown in Figs. 5 and 6, the mold has two parts 44 and 46. Mold
9 part 44 has two semicylindrical recesses 48 formed therein in the
10 shape of flanged end part 14; however, any number of recesses can
11 be formed in mold part 44 depending upon the number of medical vent
12 tubes to be made. A through hole 50 extends perpendicularly
13 downward from the bottom of each recess 48 to a bottom face of the
14 mold part to define an outer surface of shaft 12.

15 Mold part 46 has two semicylindrical projections 52 formed
16 thereon in opposed relation to recesses 48. Projections 52 have a
17 length corresponding to the length of recesses 48 but are of
18 smaller radius to be radially spaced from inside surfaces of
19 recesses 48 when the mold parts are assembled as shown in Fig. 6.
20 The space between projections 52 and recesses 48 correspond in size
21 and shape to flange 26 with the exception of cutouts 34 and 36
22 which are formed by a second pair of semicylindrical projections 54
23 that extend transversely across the center of each projection 52 in
24 opposed relation to a pair of similarly sized semicylindrical
25 recesses 56 formed in mold part 44 across recesses 48.

1 The inner diameter or lumen 22 of each shaft 12 is defined by
2 a core pin 58 disposed within hole 50. Core pin 58 includes a
3 cylindrical base 60 snugly fitted within hole 50 and a post 62 of
4 smaller diameter than the base disposed concentrically within hole
5 50 between base 60 and projection 52. Channels 64a and 64b connect
6 recesses 48 with a central opening 66 formed through mold part 46
7 to accommodate a nozzle or the like through which a polymeric
8 material can be injected under pressure.

9 In forming the medical ventilation tube 10, mold parts 44 and
10 46 are assembled as shown in Fig. 6 and held together by use of
11 clamps, threaded bolts or any other conventional means to prevent
12 separation of the mold parts when polymeric material is injected
13 into the mold under pressure. In the assembled condition, the
14 projections on mold part 46 fit within the recesses in mold part 44
15 to define cavities having the shape of flanged end portion 14, and
16 core pins 58 fit within holes 50 to define cavities having the
17 shape of shaft 12.

18 Referring now to Fig. 7, a first polymeric material 67 of
19 relatively high durometer, such as a 90 to 95 durometer C-Flex
20 material, is injected into the mold and cured in accordance with
21 the material manufacturer's recommendations to produce a molded
22 part of relatively high durometer resembling the medical vent tube.
23 The material is injected into the mold through opening 66 in mold
24 part 46 and is directed by channels 64a and 64b into the space
25 between projections 52 and recesses 48 to form a flanged end
26 portion and between core pin 58 and hole 50 to form the shaft.

Once the high durometer material has cured, mold parts 44 and 46 are pulled apart and core pins 58 are punched through mold part 44 as shown in Fig. 8 to eject the molded parts. End portion 14' of each molded part is separated from the shaft, for example by cutting across the broken line shown in Fig. 8, and the separated end portion 14' is discarded. Shaft 12 of the molded part is retained so that it can be placed over core pin 58 and positioned within the mold as shown in Fig. 9 when flanged end portion 14 of the medical vent tubes is to be formed. Since shaft 12 essentially fills the space between core pin 58 and hole 50, when a second polymeric material 69 of lower durometer than the first, such as a 45 to 55 durometer C-Flex material, is injected into the mold, only the cavity having the shape of the flanged end portion will be filled with the low durometer material. As a consequence of molding the flanged end portion 14 with the shaft 12 positioned in the mold, the flanged end portion will thermally bond with the shaft to form the medical ventilation tube 10 as shown in Fig. 10. When the low durometer material has cured, mold parts 44 and 46 are pulled apart and core pins 58 are punched through the mold part 44 as described previously to eject the medical ventilation tubes 10 from the mold.


The manufacturing process described above is exemplary of the types of processes that can be used in forming the medical ventilation tube 10; however, the shaft 12 and end portion 14 of the ventilation tube 10 can be fabricated using any suitable manufacturing process and can be secured to one another using any

1 suitable means of attachment. For example, shaft 12 could be
2 formed using other well known manufacturing methods, such as by
3 extruding a continuous length of hollow tubing and cutting the
4 hollow tubing to a predetermined length corresponding to the length
5 of the shaft. Also, shaft 12 could be made of a metal material,
6 such as stainless steel, and provided with undercuts, grooves or
7 other structural features to facilitate mechanical attachment and
8 retention of the molded end portion 14.

9 In use, the ventilation tube 10 can be placed in a myringotomy
10 opening formed in the tympanic membrane of the ear as illustrated
11 in Fig. 11, to treat persistent middle ear effusion or severe
12 otitis media. The ventilation tube 10 is preferably picked up by
13 means of a conventional forceps grasping the proximal end of shaft
14 12 and is advanced into the auditory canal C of the outer ear
15 toward the tympanic membrane M. Because shaft 12 is formed of a
16 rigid material having a relatively high durometer or hardness, the
17 shaft will resist buckling or bending caused by axial insertion
18 forces, such as those caused by contact with anatomical structures
19 of the ear. As a result, the relatively soft and flexible end
20 portion 14 can be precisely positioned adjacent the myringotomy
21 opening by manipulation of shaft 12 and, when the longitudinal axis
22 of the ventilation tube is substantially aligned with the opening,
23 the end portion of the ventilation tube can be inserted through the
24 opening. When opposed ends 40 and 42 of the flange pass completely
25 through the opening to be disposed on the opposite, middle ear side
26 of the tympanic membrane, the flange is released and will recover

its original transverse shape to prevent accidental extraction or extrusion of the ventilation tube from the opening. The ventilation tube is thus implanted in the tympanic membrane of the ear with shaft 12 placed in the myringotomy opening to maintain a passage of substantially constant diameter through the membrane to allow unobstructed drainage and ventilation of the middle ear over brief or extended periods of time. The ventilation tube can be removed by simply grasping the proximal end of shaft 12 with a forceps and extracting the end portion 14 through the myringotomy opening. As end portion 14 is withdrawn proximally through the opening, the convex side of flange 26 abuts the tympanic membrane such that opposed ends 40 and 42 of the flange are pivoted or forced together in response to the force from tissue contact. Since opposed ends of the flange are semi-cylindrical in cross-section, they cooperate to form a substantially cylindrical profile when pivoted forward thereby easing withdrawal of the ventilation tube from the tympanic membrane without enlarging the myringotomy opening.

The shaft and flanged end portion of the ventilation tube can be connected in various ways without compromising strength or performance. For example, in Fig. 12, an alternate connection is shown wherein the distal end of shaft 12 includes a recess 68 and the cylindrical section of end portion 14 includes a shoulder or step 70 joining the cylindrical section with a reduced diameter portion 72 configured to fit within recess 68. Shaft 12 can be made of a high durometer plastic or rigid metal material and is



1 held in place by use of an appropriate adhesive 74 applied to
2 shoulder 70 and/or other parts of the flanged end portion. In
3 forming the alternate connection shown in Fig. 12, flanged end
4 portion 14 is preferably stiffened by mounting on a cylindrical
5 mandrel. After adhesive 74 is applied, shaft 12 can be pushed onto
6 the stiffened end portion and left in place until the adhesive has
7 cured.

8 Another modified connection, shown in Fig. 13, involves
9 forming a step or shoulder 76 at the distal end of shaft 12 and a
10 recess 78 at the proximal end of flanged end portion 14. A reduced
11 diameter portion 80 of shaft 12 extending from shoulder 76 is
12 configured to fit within recess 78 at the proximal end of flanged
13 end portion 14 to serve as a mandrel stiffening the cylindrical
14 section of the flanged end portion. As a result, the shaft and
15 flanged end portion can be held in place with heat shrink tubing 82
16 or the like that surrounds the end portion in the vicinity of
17 reduced diameter portion 80 of the shaft thereby compressing the
18 end portion against the shaft and producing a tight frictional
19 engagement or bond. Tubing 82 is preferably made of a
20 biocompatible material of relatively thin wall thickness, such as
21 a 0.001 - 0.002 inch thick Teflon tubing. Pull strength or, in
22 other words, the force required to separate the shaft from the
23 flanged end portion, can be increased by texturing the external
24 surface of reduced diameter portion 80, for example by forming
25 grooves or a cross hatch pattern on the surface or by sand blasting
26 the surface prior to assembly.

From the above, it will be appreciated that, by use of a rigid or hard tubular shaft, the ventilation tube of the present invention can be precisely positioned within an opening formed in an anatomical structure of the body to maintain a passage through the structure over brief or extended periods of time so as to allow unobstructed drainage and ventilation through the anatomical structure. Further, by use of a relatively softer flanged end portion, the ventilation tube of the present invention can prevent accidental extrusion and allow removal without causing significant trauma to the anatomical structure or enlargement of the opening. The ventilation tube can be placed in any anatomical structure separating two regions in need of pressure equalization, such as the tympanic membrane that separates the middle and outer ears. The ventilation tube can have any configuration to fit through an opening in an anatomical structure while preventing inadvertent extrusion, including configurations utilizing T-Type or round flanges and grommet configurations wherein flanges are arranged in spaced relation along the length of the tubular shaft. By "tubular" is meant having a passage extending between open ends; and, while the ventilation tube of the present invention is described herein as having a tubular shaft of cylindrical configuration, it will be appreciated that tubular shafts of any cross-sectional configuration can be used, including elliptical and polygonal cross-sectional configurations. Further, the tubular shaft can be straight, curved or angled depending upon procedural use; and, when one or more flanges are to be mounted on the shaft,



1 the flanges can be oriented at any angle relative to a longitudinal
2 axis of the shaft.

3 The material specifications and dimensions of the ventilation
4 tube will vary according to the intended use and, as such, it will
5 be appreciated that the particular materials and dimensions listed
6 herein are merely exemplary and not meant to be limiting.

7 Inasmuch as the present invention is subject to many
8 variations, modifications and changes in detail, it is intended
9 that all subject matter discussed above or shown in the
10 accompanying drawings be interpreted as illustrative only and not
11 be taken in a limiting sense.